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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/732,703 | 12/10/2003 | Shengwen Li | ALLE0002-100 (17665) | 7421 |
| 34132 | 7590 | 09/26/2006 | EXAMINER | |
| COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508 | | | NAVARRO, ALBERT MARK | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/732,703

Applicant(s)

LI ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-26, drawn to methods of altering the degree of internalization of a Clostridial toxin, classified in class 435, subclass 172.1.
- II. Claims 27-37, drawn to methods of preventing botulinum intoxication, classified in class 424, subclass 184.1.
- III. Claims 38-51, drawn to methods of preventing medical conditions, classified in class 424, subclass 184.1.
- IV. Claims 52-57, drawn to methods of inhibiting formation of lipid rafts, classified in class 435, subclass 173.1.
- V. Claims 58-59, drawn to methods of treating a disease associated with lipid rafts, classified in class 424, subclass 184.1.
- VI. Claim 60, drawn to methods of identifying compounds, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Invention I, drawn to methods of altering the degree of internalization of a Clostridial toxin, is distinct from Inventions II-VI, since it requires additional biological reagents and parameters to create the altered molecule.

Invention II, drawn to methods of preventing botulinum intoxication, is distinct from Inventions I and III-VI, since it requires neutralizing botulinum toxin.

Invention III, drawn to methods of preventing medical conditions is distinct from Inventions I-II and IV-VI, since it requires preventing metabolic disorders.

Invention IV, drawn to inhibiting the formation of lipid rafts is distinct from Inventions I-III and V-VI, since it requires additional biological reagents and parameters.

Invention V, drawn to methods of treating diseases is distinct from Inventions I-IV and VI since it requires treating specific patients with unique symptoms, for example, Alzheimers.

Invention VI, drawn to a method of identifying a compound is distinct from Inventions I-V, since it requires additional biological reagents and parameters for detecting the compound.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

Group I and II: antibodies to caveolin-1 alpha, caveolin-1beta, caveolin-2, caveolin-3, flotillin-1, flotillin-2, reggie-1, reggie-2, stomatin, VIP36, LAT/PAG, MAL, BENE, syntaxin-1, syntaxin-4, synapsin I, adducing, VAMP2, VAMP/synaptobrevin, synaptobrevin II, SNARE proteins, SNAP-25, SNAP-23, a membrane associated Clostridial toxin receptor protein, synaptotagmin I, synaptotagmin II, GPI-anchored proteins, GM1, GD1a, GD1b, GQ1b and GT1b.

Cholesterol-reducing agents, statin, cyclodextrin, saponin, filipin.

Sphingolipid inhibitors, L-cycloserine, fumonisin B1, D-threo-1-phenyl-2-decanoylamino-3-morpholino-1-propanol.

GROUP III: muscular dystrophy, strabismus, blepharospasm, spasmodic torticollis, oromandibular dystonia, spasmodic dysphonia, rhinorrhea, otitis media, excessive salivation, asthma, COPD, excessive stomach acid secretion, spastic colitis, excessive sweating, migraine, muscle spasm, vascular disturbances, angina, neuralgia, fibromyalgia, neuropathy, pain associated with inflammation.

Group V: hepatic insulin resistance, obesity, diabetes, hematopoietic condition, immunoinflammatory condition, Alzheimers.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The species are independent or distinct because each antibody is to a distinct primary, secondary and tertiary amino acid structure, each inhibitor has a unique structure and function, and each physical or mental disorder requires a search of a subpopulation of individuals..

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 27 and 58 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.
MPEP § 809.02(a).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark Navarro
Primary Examiner
September 21, 2006